

WHAT IS CLAIMED IS:

- 1 1. A method for aerosolizing a dose of insulin,
2 said method comprising:
3 providing insulin as a dry powder;
4 dispersing an amount of the dry powder in a gas
5 stream to form an aerosol; and
6 capturing the aerosol in a chamber having a
7 mouthpiece for subsequent inhalation by a patient.
- 1 2. A method as in claim 1, wherein the insulin is
2 substantially free from penetration enhancers.
- 1 3. A method as in claim 1, wherein the insulin is
2 present in a dry powder carrier at a weight concentration in
3 the range from about 5% to 99%.
- 1 4. A method as in claim 3, wherein the powder
2 carrier comprises a carbohydrate, organic salt, amino acid,
3 peptide, or protein.
- 1 5. A method as in claim 1, wherein the insulin dry
2 powder comprises particles having an average size below 10 μm .
- 1 6. A method as in claim 1, wherein the dry powder
2 comprises individual particles including both insulin and a
3 carrier material.
- 1 7. A method a in claim 6, wherein the insulin is
2 present in the individual particles at from 5% to 99% by
3 weight.
- 1 8. An improved method for the respiratory delivery
2 of insulin, wherein the improvement comprises delivering the
3 insulin as a dry powder.
- 1 9. An improved method as in claim 8, wherein the
2 insulin is substantially free from penetration enhancers.

1 10. An improved method as in claim 8, wherein the
2 insulin is present in a dry powder carrier at a weight
3 concentration in the range from about 10% to 99%.

1 11. An improved method as in claim 10, wherein the
2 powder carrier comprises a carbohydrate, organic salt, amino
3 acid, peptide, or protein.

1 12. An improved method as in claim 8, wherein the
2 insulin dry powder comprises particles having an average size
3 below 10 μm .

1 13. An improved method as in claim 8, wherein the
2 dry powder comprises individual particles including both
3 insulin and a carrier material.

1 14. An improved method as in claim 13, wherein the
2 insulin is present in the individual particles at from 5% to
3 99% by weight.

1 15. A method for preparing a stable, dry powder
2 insulin composition, said method comprising:
3 dissolving insulin in an aqueous buffer to form a
4 solution; and
5 spray drying the solution to produce substantially
6 amorphous particles having an average size below 10 μm .

1 16. A method as in claim 15, wherein the insulin is
2 dissolved in a aqueous buffer together with a pharmaceutical
3 carrier, wherein a dry powder having insulin present in
4 individual particles at from 5% to 99% by weight is produced
5 upon spray drying.

1 17. A method as in claim 16, wherein the
2 pharmaceutical carrier is a carbohydrate, organic salt, amino
3 acid, peptide, or protein which produces a powder upon spray
4 drying.

1 18. A method as in claim 17, wherein the
2 carbohydrate is selected from the group consisting of
3 mannitol, raffinose, lactose, malto dextrin and trehalose.

1 19. A method as in claim 17, wherein the organic
2 salt is selected from the group consisting of sodium citrate,
3 sodium acetate, and sodium ascorbate.

1 20. An insulin composition for pulmonary delivery,
2 said composition comprising individual particles which include
3 insulin present at from 5% to 99% by weight in a
4 pharmaceutical carrier material and have a size below 10 μ m.

1 21. An insulin composition as in claim 20, wherein
2 the composition is substantially free from penetration
3 enhancers.

1 22. An insulin composition as in claim 20, wherein
2 the pharmaceutical carrier material comprises a carbohydrate
3 selected from the group consisting of mannitol, raffinose,
4 lactose, malto dextrin, and trehalose.

1 23. An insulin composition as in claim 20, wherein
2 the pharmaceutical carrier material comprises an organic salt
3 selected from the group consisting of sodium citrate, sodium
4 gluconate, and sodium ascorbate.

1 24. An insulin composition produced by the method
2 of claim 15.

1 25. An insulin composition consisting essentially
2 of dry powder insulin having an average particle size below
3 10 μ m.